AUG 1 8 2009

510(K) Summary

K090774

This is a 510(K) summary in accordance with CFR807.82(c).

A. Submitter Information:

Submitter: Lightmed Corporation
Address: NO.1-1, Lane1, Pao-An St. Sec. 3,
Shulin City, Taipei Hsien 23861, Taiwan
Owner/Operator Number: Mr. Gary Lee, CEO / 9040850
Contact person: Anita Chen, Regulatory Affair
TEL: +886-2-2688-1726
FAX: +886-2-2676-4920

B. Device Name:

Device Name: LightLas Family of Medical Laser System
Common name: Ophthalmic Laser, Surgical Laser
Classification name:
86 HQF, Laser, Ophthalmic
79 GEX, Laser Powered Surgical Instrument
Regulation Number:
21 CFR 886.4390, Ophthalmic Laser
21 CFR 878-4810, Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Performance standards: 21 CFR 1040.10 & 1040.11

C. Predicate Device Names:

The intended use has not changed from the predicate devices (K081704, K021550)

K081704: Selecta Family of Ophthalmic Laser System
K021550: Lumenis Selecta Duet

D. Device Description:

The LightLas Family of Medical Laser System is a fully integrated, high-performance diagnostic slitlamp and therapeutic laser delivery system. The System is also an ophthalmic surgical laser designed for performing photodisruption and photocoagulation. For ocular tissue using laser energy emitted by a Nd:YAG laser including posterior capsulotomy, pupillary membranectomy and selective laser trabeculoplasty.

The LightLas Family of Medical Laser System produces short, individual pulses of focused laser light with wavelengths of either 1064nm to 532nm, depending on the selected operational mode. Using a slitlamp microscope and aiming beam, the pulsed light is accurately targeted on a structure within the patient's eye. There are several packages for treatment selectable.

The LightLas Family of Ophthalmic Lasers is comprised of:

LightLas Lpulsa SYL-9000 (K990075): A Nd: YAG laser providing laser pulses at a wavelength of 1064 nm for use in photodisruption of ocular tissue (posterior capsulotomy and pupillary membranectomy).

LightLas SeLecTor Deux: A Nd: YAG laser providing laser pulses at a wavelength of 1064 nm for use in photodisruption or frequency doubled YAG laser pulses at a wavelength of 532nm for use in selective laser trabeculoplasty, depending on the mode selected.

LightLas LaserLink : Laser delivery adapter that may be coupled to each of the above Selecta models and connected to a currently cleared LightLas 532/561/810 retinal photocoagulator to allow use of the slit lamp to deliver 532/561/810 nm continuous wave laser energy for retinal photocoagulation.

LightLas SeLecTor Trois: A Nd:YAG laser providing laser pulses at a wavelength of 1064 nm for use in photodisruption, Frequency Doubled YAG Laser pulses at a wavelength of 532 nm for use in selective laser trabeculoplasty, or 532 nm continuous wave laser energy for retinal photocoagulation, depending on the mode selected. The Trois is a LighLas SeLecTor Deux with one of LightLas system. LightLas SeLecTor Trois suitable for follow unit:

1. LightLas 532 : K010372
2. LightLas 561: K063297
3. LightLas 810: K021538

The intended use has not changed from the predicate devices.

E. Intended Use:

LightLas Lpulsa SYL-9000:

Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including posterior capsulotomy and pupillary membranectomy.

LightLas SeLecTor Deux:

Photodisruption of ocular tissue using light energy emitted by a Nd: YAG laser, including posterior capsulotomy, pupillary membranectomy and selective laser trabeculoplasty.

LightLas LaserLink :

Laser delivery system is for use by an ophthalmologist in the treatment of ocular tissue. The laser delivery system is intended for a variety of ophthalmic uses, including the indications specified in the laser operator manual. Refer to the laser operator manual, General Intended Use section.

LightLas SecLeTor Trois: (SeLecTor Deux with LightLas 532 or 561 or 810)

Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including posterior capsulotomy, and pupillary membranectomy, retinal photocoagulation and selective laser trabeculoplasty.

The intended use has not changed from the predicate devices.

F. Technological Characteristics summary & Substantial Equivalence

The subject device, the Family of Ophthalmic Laser System, has the same intended use, general design and fundamental scientific technology as the predicate devices (K021550, K081704).

The Family of Ophthalmic Laser System uses technology substantially equivalent to

the Lumenis Selecta Duet (K021550) and Lumenis of Selecta Family of Laser System. There are no new hazards introduced by the Family of Ophthalmic Laser System as compared with the predicate devices.

G. Performance Data Summary:

The appropriate testing including safety, performance and functional testing to determine substantial equivalence of the LightLas Family of Medical Laser System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Lightmed Corporation
% Ms. Anita Chen
Regulatory Affair Committee
Director
No. 1-1, Lane 1, Pao-An St. Sec. 3
Shulin City, Taipei Hsien 23861
Taiwan

AUG 13 2009

Re: K090774
Trade/Device Name: LightLas Family of Medical Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Opthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: July 22, 2009
Received: August 6, 2009

Dear Ms. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

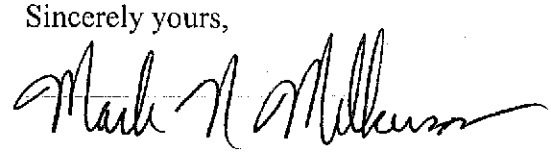
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement as Requested by FDA

510(K)Number (if Known): K090774

Device Name: LightLas Family of Medical Laser System

Indications for Use:

LightLas Lpulsa SYL-9000:

Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including posterior capsulotomy and pupillary membranectomy.

LightLas SeLecTor Deux:

Photodisruption of ocular tissue using light energy emitted by a Nd: YAG laser, including posterior capsulotomy, pupillary membranectomy and selective laser trabeculoplasty.

LightLas LaserLink :

Laser delivery system for use by an ophthalmologist in the treatment of ocular tissue. The laser delivery system is intended for a variety of ophthalmic uses, including the indications specified in the laser operator manual. Refer to the laser operator manual, General Intended Use section.

LightLas SecLeTor Trois: (SeLecTor Deux with LightLas 532 or 561 or 810)

Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including posterior capsulotomy, and pupillary membranectomy, retinal photocoagulation and selective laser trabeculoplasty.

The intended use has not changed from the predicate devices (K081704)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDR, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use:_____

(Per 21 CFR 801.109)

Neil R. Ogden for mkm

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090774